



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

December 3, 1986

*[Handwritten mark, possibly initials]*

Mr. Ronald Wilson  
Health Assessment Policy Staff  
Office of Health Affairs  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U. S. Patent No. 4,215,215, issued July 29, 1980, was filed on November 21, 1986 under Title II of Public Law 98-417.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC 156.

*C.E. Van Horn*

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Charles E. Van Horn  
Director, Group 120  
U. S. Patent and Trademark Office

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